Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed September 21, 2009. Currently, claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 remain pending. Claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1, 2, 4-12, 14-16, 18-26, 28, and 29 were rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. (U.S. Patent Application Publication No. 2003/0004537), hereinafter Boyle, in view of Dubrul et al. (U.S. Patent No. 6,221,006), hereinafter Dubrul. Applicants note that the Boyle reference is a published application rather than an issued U.S. Patent. After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03).

As discussed previously, and current acknowledged by the Examiner, nowhere does Boyle appear to disclose "the expandable member is a braided member that also extends proximally of a distal end of the elongated shaft member", said shaft member of Boyle being identified as element 112, further identified as a sheath in the discussion of the cited Fig. 12. As described at paragraph [0060] which appears to provide the only detailed description of the embodiment of Figs. 12 and 13, sheath 112 appears to consist of only two portions: "In this particular embodiment, the distal tip portion 114 can be made from a material which is different from the remaining portion of the sheath 112. For example, the tip material can be made from a material which is even more elastic than the portion 118 which forms the remainder of the sheath 112." (Emphasis added.) Accordingly, Fig. 12 of Boyle appears to disclose a sheath 112 having a uniform diameter portion 118 and a distal tip 114 of the same uniform diameter in the undeployed state.

Boyle appears to not disclose an elongated shaft having "a flared distal section" as recited in the independent claims, in those embodiments having a differentiated tip region.

The Examiner has also made reference to a separate embodiment found in Fig. 1 of Boyle with the assertion that portion 22 of that device may be considered the proximal end of the elongated shaft corresponding to portion 118 of the embodiment of Fig. 12. This assertion does not appear to be supported by the disclosure. In particular, the rapid exchange sheath of Figs. 1-3 are characterized a rapid exchange-type sheath while that of the later design found in Figs. 4 and 5 (and higher) are said to be "a full-length sheath" which appears to be consistent with the indication that section 118 is representative of the full length of the sheath as quoted above. (See paragraph [0057].) To the extent that the tip-less embodiment of Figs. 4-5, (or the related tip-less embodiment of Figs. 6 and 7) is informative, it should be noted that it consists of low expansive material which provides column strength and axial stiffness to the housing 62, thus indicating that the housing of Boyle does not rely upon axial compression and would be expected to resist such axial compression. This would appear to teach away from any modification which relies upon axial compression of an axially stiff sheath. As discussed previously, any reduction in length of the sheaths of Boyle appears to be the incidental result of radial expansion rather than the cause of the radial expansion.

The embodiment of Fig. 1 appears to include an expandable housing portion 26 which is sized to contain the medical device (embolic filter) as shown in Fig. 2. The portion of the sheath 22 indicated by the reference numeral is said to be "dedicated to the lumen 28 which holds the mandrel and the rapid exchange lumen 32 that receives the guidewire of the embolic filtering device". (See paragraph [0048].) Accordingly, portion 22 does not appear to correspond to a "braided member including a plurality of filaments and defining a radially expandable inner lumen configured to receive and encapsulate the intravascular device therein" as recited in independent claims 1, 15, and 29 with some variation in the language employed. Only the portion 26 as depicted in Fig. 1 appears to expand to engulf the medical device. That embodiment does not appear to include the braid of the pending claims or the ring member 116 of the cited Fig. 12. It is only in the "full-length" embodiments of Figs. 8-13 that a modified tip portion, upon which the

Examiner appears to rely, appears to be present and so only those embodiments may be modified by the teaching of Dubrul as proposed.

The tip portion 114 contains biasing member ring 116 which the Examiner asserts most nearly corresponds to the braid of the pending claims and which is to be replaced by an element from Dubrul in the suggested combination. Ring 116 is said (paragraph [0060]) to be similar to the rings (104) of Figs. 10 and 11, the operation of which is characterized as follows at paragraph [0059]: "ring member 104 has undulations which allow the ring member to expand radially outward as shown in FIG. 11 to increase the diameter of the housing portion 100". The rings then "contracts the tip once the tip extends over the component to be restrained, such as the filter basket of an embolic filtering device" when the filter is contained within the highly stretchable materials of the respective sheaths 102 and 118. Thus there appears to be no significant axial contraction of the tip section other than that imposed by the conservation of volume of the expanded tip section and so no indication that axial compression results in radial expansion.

In turning to Dubrul to address the deficiencies of Boyle, the Examiner asserts that the text at column 12, line 5:

> "the umbrella(s)/TRAP(s) like mechanism(s), if used is"

and at column 14, lines 10-11:

> "PYTHON channel may be coated of encased in an elastomeric or other covering. Further, the PYTHON channel may"

teaches, "a distal braided member comprising a plurality of filaments encased in an elastomeric jacket that may include a urethane or silicone". The Applicants respectfully disagree with that characterization of the passages cited.

The Examiner continues, referring to col. 14, lines 44-45:

> "The tubular braid is preferably formed as a mesh of individual non-elastic filaments (called yarns in the braid-" ing industry).

by suggesting that the text indicates that, "the plurality of filaments are multi-filar threads (a mesh of individual filaments called yarns" . The Applicants again disagree with the Examiner's reading of the passage in question and with the resulting interpretation of a term of art in braiding. Instead, the Applicants believe that the passage refers to each of the individual non-elastic filaments (in a woven braid mesh) as a "yarn" as the term is used in the braiding industry regardless of whether the "yarn" is a single filament or a group of filaments interwoven by the so-called "yarn carriers". Thus, Dubrul does not appear to disclose a braid comprising multi-filar filaments as that term would be understood by one of ordinary skill in the art.

Following a brief diversion into a discussion of the various braids of Dubrul, the Examiner returns to column 15, lines 34-40 which are characterized as teaching that the braided member may be placed in an expanded state when subjected to a compressive force and in a relaxed state when subjected to a tensile force. The assertion is then made that, "The substitution of one known element (expanding member and elastomeric jacket as shown in Boyle) for another (expanding member and elastomeric jacket as shown in Dubrul) would have been obvious to one of ordinary skill in the art at the time of the invention".

The Applicants respectfully disagree with the functional equivalence of characteristics attributed to the respective elements by the Examiner. The rings 116/104/coil spring 94, as well as the "highly elastic expansion members", of Boyle appear to be elements which "when a outward radial force is applied to the inner surface 96 of the housing portion 90, the coil spring expands outwardly allowing the housing portion to expand as needed to capture the filter basket". (sic) The ring members are normally biased to the collapsed diameter. Accordingly, the device of Boyle appears to respond to simple radially directed internal forces to elastically expand the mouth of the device and the elastic radial return to close the mouth as the filter is engulfed. Were one to replace the elastically responsive element of Boyle by a braid of Dubrul, even one which might respond to compressive forces by expanding radially, it would appear that the braid would not be subject to a subsequent elongational force, which appears to be required to constrict the braid, following the engulfing of the filter and so one of ordinary skill in the art would not be motivated to make the proposed substitution. Further, substituting axial compression for outward radial force to expand and an unspecified and apparently unavailable axial extension for radial elastic recovery would impermissibly alter the operating principle of Boyle. (MPEP 2143.01, VI.) For at least these reasons Boyle in view of Dubrul does not appear to establish a *prima facie* case of obviousness.

The Examiner then acknowledges that Boyle as modified by Dubrul, "fails to disclose the braided member also extends proximally of the distal end of the elongated shaft member" and relies upon the Applicant's own disclosure to provide the teaching necessary to overcome this acknowledged deficiency of the combination of Boyle in view of Dubrul. In discussing this aspect of the claims, the Examiner has asserted that the Applicants have not disclosed any benefit of doing so. Attention is directed to page 4, lines 8-10 which indicates that the proximal portion of the braid facilitates bonding of the braided member to the retrieval catheter.

For all of the reasons acknowledged and discussed above, the combination of Boyle and Dubrul does not appear to teach all limitations of the claims or to establish a *prima facie* case of obviousness as applied to independent claims 1, 15, and 29 and Applicants respectfully request that the rejections be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Accordingly, claims 2, 4-12, 14, 16, 18-26, and 28, which depend from nonobvious independent claims 1, 15, and 29 respectively, also are believed to be nonobvious and Applicants respectfully request that the rejections be withdrawn.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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